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Portable Hand Held X-Ray Instrument (Lixiscope)

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

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Public Health Service Assessment

Portable Hand Held X-Ray Instrument
(Lixiscope)

1985

INTRODUCTION

The lixiscope is a portable real-time x-ray imaging device which is battery powered. It produces a fluoroscopic picture of any part of the human anatomy which can be inserted in the eight inch space between the energy source and the viewing mechanism. The radiation energy source is the isotope iodine-125. The radiation energy beam is directed onto a viewing screen on the body of the unit thus preventing any direct exposure to the operator at the viewing end. A Polaroid camera may be used to make a record of the image on the screen.

BACKGROUND

LIXI is an acronym for Low Intensity X-ray Imaging. The invention of the lixiscope is a direct product of the United States space program. In the mid-1970's a team of scientists at the Goddard Space Flight Center of the National Aeronautics Space Administration (NASA) developed a system for making photographic images of celestial objects that emitted energy in the x-ray and gamma ray region of the spectrum. The ability of this system to produce high quality visual images from minute amounts of spectral radiation was considered to be an important technological breakthrough. The original NASA technical memorandum of 1978 describes the concept of each x-ray photon being converted into a large number of visible light photons by means of a

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phosphor screen (1). That screen is in contact with an input fiberoptics face plate of a second generation night vision image intensifier. The night vision intensifier situated between an input fiber optics face plate and an output microchannel plate (MCP) multiplies the photon electrons released from the screen with an average gain of roughly 10^3. The output plate brings the final intensified image to a plane flush with the viewing surface of the intensifier. This viewing surface can then be coupled with an image recording device such as those using fast instant processing films. The entire original intensifier was powered by a single 2.7 volt battery. In that technical memorandum, Yin and Seltzer, concluded that the results demonstrated the feasibility of a low dose, compact, rugged, and fully portable x-ray image intensifier system suitable for both laboratory and field use.

Later that same year Yin and Trombka (2) noted that the basic elements of the system, i.e. the radiation source, the scintillator phosphor converter, and the microchannel plate visible light image intensifier as described above are separable entities and can be replaced for the purposes of development, or varied in strength. In 1979 Yin, Trombka, and Seltzer described further progress in building a lixiscope which demonstrated the feasibility of a modular approach to x-ray imaging in small format applications (3). They suggested that because the lixiscope is modular in concept, and the scintillator is physically independent of the imaging intensifier, the user has a great deal of freedom in the choice among phosphors or scintillators as well as a choice among intensifier tubes having various photo cathode characteristics.

The radiation source used in the imaging system is iodine-125 which has a half life of 60 days. The output image can be viewed comfortably in subdued room light or in brighter light if a small cylindrical hood is used. The imaging capacity is initiated by depressing a spring loaded trigger which rotates the radiation source capsule to align it with a hole in the protective covering so that a collimated x-ray beam emanates.

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The first human application of the lixiscope was in dental radiography. Yin and Trombka, claimed that with the lixiscope a collimated intraoral source could significantly reduce the unnecessary exposure produced by conventional radiography, and permit a wider variety of uses as well as allow real-time observation of endodontic procedures.

In 1980 Yin, Trombka, and Seltzer described an industrial prototype for operation in the 20 to 200 kilo electron volt (keV) range (4). This is much higher than the level of 27 keV used in today's medical model. The result provided improved spacial resolution and was described as being a compact and rugged device eminently suited for possible low flux industrial imaging applications. Later the same year they reported a model with improved characteristics of single x-ray and gamma ray photon counting and imaging, as well as good spacial and temporal resolution (5).

Chung and Tsang in 1981 used a comparable lixiscope for various problems in crystallography (6). The spacial resolution of their MCP intensifier was on the order of 30 lines pairs per mm. for visible light inputs. However, the overall final spacial resolution was limited by the nature of the x-ray scintillator to 4-5 line pairs per mm. This level is comparable to conventional fluoroscope devices. They noted that the lixiscope image can be recorded not only with a polaroid camera but that the intensified visible light output can be coupled to video devices. The entire device including two size AA batteries weighed 1 1/2 pounds. The model currently in use for medical purposes weighs approximately 5 1/2 pounds.

There are three variations in the bar arm which holds the sealed isotope source holder away from the main housing. The variations in instrumentation affect the distance between the two components and therefore the size of the body part which can be examined. The first is a straight distance bar arm. It has a three inch maximum distance. The second is a bar arm which is flattened and allows bench mounting or carrying case mounting of the device. It has a capacity of six inches. The third is a bowed bar arm allowing for an eight inch insertion of target for examination. All models

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are activated by a trigger and the radiation source is housed in noncorrosive stainless steel. The iodine 125-isotope is a standard size producing energy of 27 KeV. The electrical power source used in the commercial model is two 1.5 volt size "C" alkaline batteries. Resolution is 3 line pairs per mm. The polaroid recording camera is an optional accessory. The image of the target being examined is inverted on direct vision of the screen. Safety features include an automatic shut off and heavy shielding of the isotope.

RATIONALE

Proponents of the lixiscope claim that it can be used in clinical situations where other x-ray imaging devices are not available. No outside power source is needed and the device is light-weight and portable. Radiation exposure is claimed to be less than with standard x-ray procedures. They suggest that deployment of the device in the appropriate situations could reduce hospitalization and emergency room calls if the presence of foreign objects or fractures can be eliminated as a result of injury immediately following the trauma in sports, accidents etc. Proponents contend therefore that ease of use, extraordinary mobility, accuracy, clarity of the image with intensification, reduction in x-ray exposure of the patient, and cost savings make the device an important new addition to the armanentarium of practitioners who employ imaging devices.

REVIEW OF THE LITERATURE

In 1978 NASA convened a lixiscope conference at the Goddard Space Flight Center in Greenbelt, MD. In addition to reviewing the technical status of the lixiscope the program included a series of papers on development, known medical clinical applications, and the prospects for further applications. Press described his limited evaluations of the lixiscope and commented particularly on its utility in the emergency

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room (7). He stated that in such a setting there are excellent opportunities to eliminate long waits for many patients, particularly those with hand injuries. The physician could provide immediate triage for such problems by examining several patients quickly and determining which can be discharged and which ones need further x-ray examination. He thought the device offered opportunity to identify, by quick observation, any fractures or other pathology that would not ordinarily be discovered without conventional imaging. Another potential application was responsible use at sports events particularly for the teams of smaller o ganizations where standard x-ray equipment is not available at the stadium. Orthopedic uses of the lixiscope were described by Walden, who presented a series of pictures showing fractures of various degree of the hands and fingers (8). He considered it to be an important screening device so that patients would not be discharged from the emergency room without further therapy if required. He suggested that further orthopedic evaluation, including some clinical trials, was indicated.

Webber, in discussing his preliminary observations in dental research, stated that objective clinical evaluation would require formal testing involving a research protocol (9). Polaroid pictures showed the ability of a lixiscope to demonstrate periodontal lesions. During root canal surgery, the degree of endodontic invasion of surgical instruments is made visible enabling the operating surgeon to have greater accuracy. He predicted that the future of the lixiscope in dentistry would depend on how well it performs in actual clinical situations particularly when used as a fluoscope during operative procedures. Reiskin suggested that in dental surgery the lixiscope can be a primary diagnostic device. It could be of even greater importance when used in conjunction with, or in support of, operative procedures, particularly those which are endodontic in nature (10). He thought, however, that the lixiscope at that point in time (1978) did not have sufficient resolution to function as a primary diagnostic tool for most dental needs.

Spackman (11) noted the obvious compatibility of a pediatric patient's size with the low dose portable radiation device. Particularly in premature infants, the lixiscope

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reduces the amount of radiation to which infants are exposed. In addition he considered it to be a marked advance in the armamentarium of those who must transport newborn infants to pediatric regional centers from satellite obstetrical delivery sites by aiding in clinical evaluation while in transit.

Weissman described the recent surgical orientation of podiatry (12). He reported that the trend is toward minimal incision surgery, particularly in the removal of excressences caused by small bone prominences such as an exostosis or a hypertrophy of a phalanx. During surgical procedures there is a marked advantage ensuring that the surgeon is exploring the right place and removal of bone is being accomplished to the proper degree.

In 1979, Justice demonstrated for the Office of Research and Development of the Indian Health Service, PHS the feasibility of transmitting clinically useful lixiscope images via cable television (13). The transmission of diagnostically valuable radiograph television images over ordinary long distance telephone lines also demonstrated the value of the slow scan transmission components.

Tansey, in 1981, described the increasing use of the lixiscope in sports medicine to diagnose and treat injuries of the hand, foot, ankle, wrist, and elbow at the time they occur(14). The lixiscope enables the orthopedic surgeon to carry out immediate screening or diagnosis at the scene of the injury. In his opinion, this enabled the physician to differentiate quickly between sprains and fractures. It is also felt to be useful in finding metallic and other radio-opaque foreign bodies in the hand or foot. Use of the device can be carried over to the operating room or emergency room for the purpose of removing those objects. The lixiscope can also be employed in the physician's office to diagnose and treat emergency sports injuries without having to transport the patient to the x-ray department or to the hospital for x-ray studies.

In 1982 Gorecki et al. reported on a study which identified and evaluated the potential utilization of the mobile prototype low intensity x-ray imaging device in podiatry (15). They carefully evaluated five randomly selected patients for varying

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articular and soft tissue diseases as well as skeletal deformities. Two case studies were presented in considerable detail. One was a case in which a diagnosis of early osteomylitis was determined by lixiscope. The pathology had not been evident in comparative standard x-rays. The resolution was thought, in certain instances, to be superior to the conventional x-ray. Further advantage was noted in the ability to move the lixiscope about to get a series of oblique pictures in real time. In the second case certain points of impingement were visualized in a patient with a hallux valgus deformity of many years duration. The results were compared with a standard dorso-plantar x-ray. The advantage of the lixiscope was noted to be its ability to visualize points of impingement, limitations to motion, and smoothness of motion, due to continuous imaging which is not possible by conventional x-rays. The authors suggested that use of the lixiscope, rather than other imaging modalities, will result in a cost saving in care of podiatric patients.

DISCUSSION

The Nuclear Regulatory Commission (NRC) has the authority to regulate the use of radioactive materials which was granted to it by the Atomic Energy Act of 1954. Since the lixiscope's source of radiation is iodine-125, NRC regulates the possession and use of the material. When NRC grants a specific license to anybody to use an isotope source or device, the instrument must be evaluated from the standpoint of its safety, not only to the individual using it, but to the general public. The NRC responsibility deals with the safety of the user, the handler, i.e., a non-user handler of a device, and the public.

NRC approved the lixiscope for licensing purposes in April of 1981. In discussing its safety features, NRC stated that it was unlikely that any person would be exposed to excess doses of radiation. Furthermore, it was noted that the sealed radiation source could not be removed from its shielded capsule without special tools. Also, the device

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was expected to withstand any accident, in conditions likely to occur during transportation, storage or use. Since the half life of iodine-125 is only 60 days, the radiation output of the device diminishes in six months to where the dose rate would be less than half a milli-roentgen per second. Under Section 510(k) the FDA permitted marketing of the lixiscope as a medical device in 1982. The device was determined to be substantially equivalent to fluoroscopy devices in medical use prior to the Medical Device Amendments of May 28, 1976 to the Food, Drug and Cosmetics Act.

Activating the lixiscope with the trigger rotates the source and aligns it with an aperture in its stainless steel capsule. The action allows a collimated beam to be directed toward the scintillator. Releasing the trigger allows a spring mechanism to rotate the source back to its covered position. The locking mechanism consists of holes in the capsule in line with a hole in the rotating mechanism. A steel shaft is threaded through both to prevent rotation and exposure. The procedures require that the key be kept separate from the device when locked.

There is no leakage when the machine is not being used because of the automatic shutoff device which shields the I-125 source. When the device is being used a beeping sound is heard every ten seconds to alert the user that the source is exposed. The lixiscope is expected to limit exposure intensity and duration to the patient. Thus it is estimated that when the lixiscope is used, the exposure is limited to the portion of the extremity directly in view. The segment itself receives less exposure per minute than from an x-ray or fluoroscopy machine. During a typical conventional x-ray of the hand the patient absorbs 80 milliroentgens (mR). Using a lixiscope, during a one minute examination the patient absorbs less than 19 mR.

The NRC did a considerable review of the possibilility of the lixiscope exposing the surrounding environment by unintended leakage or scatter of ionizing radiation. They concluded that when a sample was placed in the focused beam, the maximum dose rate from scatter at 5cm. from the lixiscope viewing screen was less that 0.05 milliroentgens per hour (mr/hr); at 5cm. from the sample and at right angles to the sample the dose rate

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was approximately 1.5 mr/hr. This was considered to be well within acceptable NRC standards. Also, as with most other isotope sources, each lixiscope must be leak tested by an individual or company licensed to do such testing, at intervals not to exceed six months. The testing techniques must be capable of detecting the presence of 0.005 microcurries of contamination. The NRC data on health physics was evaluated by FDA and considered to be adequate in arriving at the decision to approve the device for medical use.

The clinical effectiveness of the lixiscope is difficult to evaluate because of the lack of any published reports of formal clinical trials. Isolated small groups of cases have been reported and the last medical report was that of Grocki in 1982 (15). It has been the position of advocates of the device that clinical trials are not necessary.

The position of the National Institutes of Health is that before the technology is used on a wide scale better data is needed regarding patient exposure and image quality. The Veterans Administration has voiced concerns about the possibility of misdiagnoses due to the limitations of the device, the lack of a permanent record, and the potential radiation hazards. In addition they were concerned about the accidental use by children or other inexperienced individuals if it is left available to them. It was noted that the image quality deteriorates as the operator examines thicker parts of limbs and therefore the possibility of mistaken diagnosis rises.

Information on this technology was sought from knowledgeable sources both directly and through a notice published in the Federal Register (16). Certain private sector organizations forwarded comments. The Academy of Ambulatory Foot Surgery believes the lixiscope will actually result in patients being subjected to lower levels of radiation. In addition it was felt that there would be a shift to outpatient surgery for many foot problems. The American Academy of Family Physicians presented the informal conclusions of some members of the Academy's commission on Public Health and Scientific Affairs. Their conclusions are that the lixiscope has applications in sports medicine, pediatrics, and possibility podiatric medicine. In the Medicare age group it

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was believed that podiatry would be a major user. Rural patients might be better served with conventional x-ray equipment. A concern was expressed about the possibilty of a breakdown in the shielding of the x-ray source. The American Academy of Orthopedic Surgeons forwarded a comment which questioned the image quality and the lack of a permanent image for retention. In general, the lixiscope was felt by them to be of little use in established diagnoses. The Academy however, noted that it had not done a formal technology assessment. The American Association of Podiatric Medicine Colleges forwarded letters from various colleges which generally regard the use of the lixiscope as being an extremely practical and invaluable unit in ambulatory surgery.

SUMMARY

The lixiscope is a portable real-time x-ray imaging device which is battery powered. It produces a fluroscopic image of any portion of the human anatomy which can be inserted into the eight inch space between the radiation source and the viewing mechanism. The radiation energy source is iodine-125 which has a half-life of 60 days. The lixiscope is a direct product of the United States space program where it was determined that very small amounts of x-ray photons can be converted into a larger number of visible light photons by means of a phosphor screen. A night vision image intensifier then multiplies the photons into a visible image which may be viewed directly or captured on instant processing film.

There are no controlled clinical trials comparing the lixiscope with other imaging devices. There are, however, reports of its use in various clinical situations with proponents suggesting that its lightweight portablility provides certain advantages. Emergency room triage can be accomplished quickly and accident scene and sporting event fractures may be diagnosed on site. Podiatric surgery may be enhanced because an unlimited number of oblique views can be obtained in real time.

The Nuclear Registry Commission (NRC) regulates the possession and use of the

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radiation source material and licenses operators of the lixiscope. The FDA permitted marketing of the lixiscope as a medical device in 1982.

The National Institutes of Health suggest that better data are needed regarding patient expsoure to radiation and image quality. The Veterans Administration notes the lack in many instances of a permanent image for patient progress monitoring. Private sector organization comments in general point out the usefulness of the lixiscope in rural settings, accident scenes, sports medicine and in the discovery and removal of foreign bodies.

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The lixiscope is a portable real time x-ray imaging device which is battery powered. It produces a fluoroscopic picture of any part of the human anatomy which can be inserted into the 8 inch space between the energy source and the viewing mechanism. The radiation energy source is the isotope Iodine-125. Small amounts of x-ray photons are converted into a larger number of light photons. These in turn are multiplied into a visable image by a night vision image intensifier. Its portability allows its use in sites where standard imaging equipment is not available. Also, the patient is exposed to less radiation per minute of use. The FDA permitted marketing of the lixiscope in 1982. The Nuclear Regulatory Commission requires a personal license for its use and the lixiscope itself must be certified every 6 months against leakage. Use of the lixiscope has been tried in many clinical situations. Its widest acceptance is in surgical podiatry. Physicians' organizations do not recommend it to replace conventional imaging devices in most instances. There is general agreement, however, that its light weight portability provides advantages in certain situations such as accident scenes, emergency room triage, rural settings and in sports medicine.

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